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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,920	11/21/2001	Roberto A. Macina	DEX-0291	2846

7590 07/27/2004

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,920	MACINA ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121: Based on the disclosure at page 1 of the specification, the Office determines that each of the newly identified nucleic acid molecules i.e. SEQ ID NOs 1-164, and each of polypeptides encoded by the 164 different nucleic acid molecules are different products.

Groups 1-164. Claims 1-5, 7-9, 15 in part, and 17 in part, drawn to each of nucleic acid SEQ ID NOs 1-164, vector, host cell, kit, vaccine comprising nucleic acid, classified in class 536, subclass 23.1, and others.

Each SEQ ID NO is a different invention.

Groups 165-328. Claim 6, drawn to method of using SEQ ID NOs 1-164 for detection of lung-specific nucleic acid, classified in class 435, subclass 6.

Groups 329-492. Claims 10, 11, 15 in part, 17 in part, drawn to polypeptides encoded by SEQ ID NO:1-164, vaccine comprising polypeptide, classified in class 530, subclass 350, and others.

Groups 493-656. Claim 12, drawn to antibody specifically binds to each of the protein encoded by SEQ ID NO:1-164, classified in class 530, subclass 387.1.

Groups 657-820. Claim 13, drawn to method of determining a lung specific proteins using each of the antibody capable of binding to the protein encoded by SEQ ID NO:1-164, classified in class 435, subclass 7.1.

Groups 821-984. Claim 14 in part, drawn to method of diagnosing and monitoring lung cancer using each of SEQ ID NO:1-164, classified in class 435, subclass 6.1.

Groups 985-1148. Claim 14 in part, drawn to method of diagnosing and monitoring lung cancer using each of the proteins encodied SEQ ID NO:1-164, classified in class 435, subclass 7.23.

Groups 1149-1312. Claim 16, drawn to method of treating lung cancer by administering each of the antibodies produced by the proteins encoded by SEQ ID NOs 1-164, classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups 1-1312 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different nucleic acids represented by different SEQ ID NOs in groups 1-164 are different products because they have different chemical structures as evidenced by the different SEQ ID NOs, and they encode different proteins (groups 329-492) with different biological functions and bind to different antibodies in groups 493-656. Thus, groups 1-656 are different inventions. Further, each of method groups are different inventions because they use different active ingredient products and/or different biomarkers to accomplish the purpose stated in the preamble of the claims.

Invention groups 1-164 (all nucleic acid products) and invention groups 165-328 (all method using the nucleic acid products), invention groups 821-984 (method of lung cancer diagnosis using the nucleic acid products) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the 164 different nucleic acid products as claimed can be used in a materially different process of either detecting lung-specific nucleic acids, or diagnosing lung cancer.

Invention groups 329-656 (all protein products) and invention groups 985-1148 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) each of the products as claimed can be used in a materially different process of using each those products (MPEP § 806.05(h)). In the instant case each of the products as claimed can be used in a materially different process such as making an antibody specifically binding each of the proteins.

Invention groups 493-656 (all antibody products) and the method invention groups 657-820, and the method invention groups 1149-1312 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) each of the products as claimed

can be used in a materially different process of using each those products (MPEP § 806.05(h)). In the instant case each of the products as claimed can be used in a materially different process of either detecting lung specific proteins as in groups 657-820, or treating lung cancer in groups 1149-1312.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

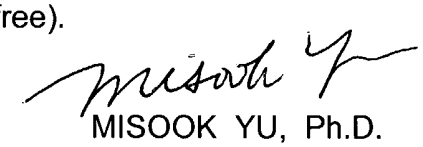
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MISOOK YU, Ph.D.
Examiner
Art Unit 1642